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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,862	03/26/2004	Feng Chen	V0690.0025	7593
32172	7590	06/10/2005	EXAMINER	
DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP 1177 AVENUE OF THE AMERICAS (6TH AVENUE) 41 ST FL. NEW YORK, NY 10036-2714			BARNHART, LORA ELIZABETH	
		ART UNIT		PAPER NUMBER
				1651

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/809,862	CHEN, FENG
	<b>Examiner</b>	<b>Art Unit</b>
	Lora E. Barnhart	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 04 May 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Prior art references can be found in a prior Office action, unless otherwise noted.

### *Claim Objections*

The objections to the claims are withdrawn in light of the claim amendments.

### *Claim Rejections - 35 USC § 112*

Claims 1-13 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "a carbon:nitrogen weight ratio of at least about 18", but as noted in the Office action mailed 1/12/05, it is not clear how this ratio was calculated. The term "weight ratio" may refer to a ratio of the weights of the components added to the medium (e.g. weight of glucose vs. weight of sodium nitrate) or to the ratio of the molecular weights of the components. As was pointed out on the first Office action, while Figure 3 discloses various carbon:nitrogen ratios (18, 55, 90, and 180), it is not clear how these values are derived from the provided amounts of glucose (10, 30, and 50g/L) and sodium nitrate (0.75g/L). Clarification is required; that is, applicant is asked to **particularly point out** the calculations employed to arrive at the numbers in Figure 3.

***Claim Rejections - 35 USC § 102***

The rejection of claims 1-16 under 35 U.S.C. 102(a) as being anticipated by Ip et al. is withdrawn in light of the Declaration by inventor Chen and non-inventors Ip and Wong received by the Office on 5/4/05.

The rejection of claims 1-16 under 35 U.S.C. 102(f) is withdrawn in light of the Declaration by inventor Chen and non-inventors Ip and Wong received by the Office on 5/4/05.

Claims 1, 2, 4-6, 8-12, 14, and 16 remain rejected under 35 U.S.C. 102(b) as being anticipated by U.S. '502. The claims are drawn to a process for producing astaxanthin comprising cultivating *Chlorella* in the dark in a medium having a carbon:nitrogen ratio of at least about 18. In some dependent claims, the medium comprises glucose.

As detailed on the first Office action, U.S. '502 teaches a process comprising cultivating *Chlorella pyrenoidosa* in the dark in a medium comprising 60g/L glucose and 2g/L potassium nitrate (weight ratio=30, for example). Applicant has argued that U.S. '502 teaches a method of producing lutein (another carotenoid) and does not teach or suggest a method of producing astaxanthin.

To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See *id.* and *Verdegaal*

*Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). **Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art.** See *Titanium Metals*, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See *id.* at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *id.* at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others..., by one who has discovered its...useful properties."); *Verdegaal Bros.*, 814 F.2d at 633.

This court's decision in *Titanium Metals* illustrates these principles. See *Titanium Metals*, 778 F.2d at 775. In *Titanium Metals*, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." *Titanium Metals*, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting, "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain

inherent properties." *Id.* at 782. This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." See *Atlas Powder Co. v. IRECO Inc.*, 51 USPQ2d 1943 (Fed. Cir. 1999).

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly **or** inherently. A reference includes an inherent characteristic **if that characteristic is the natural result flowing from the reference's explicitly explicated limitations.** *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

In the instant case, the production of astaxanthin is a natural result of the process of U.S. '502, namely cultivating *Chlorella* in the dark in a medium having a carbon:nitrogen ratio of at least about 18. Applicants are incorrect in arguing that the anticipatory rejection is improper. In the absence of a particularly recited step in which astaxanthin is recovered, the instantly claimed process is anticipated by U.S. '502.

#### ***Claim Rejections - 35 USC § 103***

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. '502. As detailed above, the claims are drawn to a process for producing astaxanthin comprising cultivating *Chlorella* in the dark in a medium having a

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carbon:nitrogen ratio of at least about 18. In some dependent claims, the medium comprises glucose. In some dependent claims, the *Chlorella* is *C. zofingiensis*.

As discussed above, U.S. '502 teaches a process comprising cultivating *Chlorella pyrenoidosa* in the dark in a medium comprising glucose and having a carbon:nitrogen weight ratio of 30, for example. U.S. '502 does not teach the use of *C. zofingiensis*.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' process differs, and if so to what extent, from the process discussed in U.S. '502. Accordingly, it has been established that the prior art process, which teaches the cultivation of *C. pyrenoidosa*, which has the same genus identification as the instantly claimed *C. zofingiensis* and shares the ability to produce astaxanthin in the dark, demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed process that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a new process is not disclosed in a reference does not make the known process patentable. The new process possesses inherent characteristics which might not be displayed in the tests used the reference. Clear evidence that the process of the cited prior art do not possess a critical characteristic that is possessed by the claimed process would advance prosecution and might permit allowance of claims to applicants' process.

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### ***Conclusion***

***No claims are allowed. No claims are free of the art.***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

(eb)

SANDRA E. SAUCIER  
PRIMARY EXAMINER

